CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020916

ENVIRONMENTAL ASSESSMENT AND/OR FONSI

ENVIRONMENTAL ASSESSMENT

AND

FINDING OF NO SIGNIFICANT IMPACT

FOR

Prilosec®

(Omeprazole)

Capsules

NDA 20-916

Food And Drug Administration
Center For Drug Evaluation And Research
Division of Special Pathogen and
Immunologic Drug Products (HFD-590)

FINDING OF NO SIGNIFICANT IMPACT

NDA 20-916

Prilosec®

(omeprazole)

Capsules

The National Environmental Policy Act of 1969 (NEPA) requires all Federal agencies to assess the environmental impact of their actions. FDA is required under NEPA to consider the environmental impact of approving certain drug product applications as an integral part of its regulatory process.

The Food and Drug Administration, Center for Drug Evaluation and Research has carefully considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment and that an environmental impact statement therefore will not be prepared.

In support of their new drug application for Prilosec® (omeprazole) Capsules, Astra Merck, Inc. has prepared an environmental assessment in accordance with 21 CFR Part 25 which evaluates the potential environmental impacts of the use and disposal of the product. Detailed environmental information for omeprazole was previously provided in support of NDA 19-810.

Omeprazole is a drug which is already available in the U.S. This application provides for the use of Prilosec®, in combination with amoxicillin and clarithromycin, in the treatment of *H. pylori* infection and duodenal ulcer disease.

Omeprazole may enter the environment from patient use and disposal. It is expected to enter predominantly into the aquatic environment. The expected environmental aquatic concentration (EEC) from use is expected to be significantly less than the expected introduction concentration (EIC) because the compound undergoes rapid hydrolysis and photolysis. As the drug is expected to persist in the environment for some time, the toxicity of omeprazole to aquatic organisms was characterized. The results show that omeprazole is not expected to be toxic to aquatic organisms at the expected environmental concentration.

At U.S. hospitals and clinics, empty or partially empty packages will be disposed according to hospital/clinic procedures. From home use, empty or partially empty containers will typically be disposed of by a community's solid waste management system which may include landfills, incineration and recycling, while minimal quantities of unused drug may be disposed of in the sewer system.

The Center for Drug Evaluation and Research has concluded that the product can used and disposed of without any expected adverse environmental effects. Adverse effects are not anticipated upon endangered or threatened species or upon property listed in or eligible for listing in the National Register of Historic Places.

/S/

1/13/98
DATE

PREPARED BY
Nancy B. Sager
Office of Pharmaceutical Science

/S/

1-14-98
DATE

CONCURRED
Eric B. Sheinin, Ph.D.
Director, Office of New Drug Chemistry
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL